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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

02/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 29, 30, 32, 34-36, 38, 40-44, and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka (US 6,738,674, hereinafter "Osypka") in view of Huepenbecker et al. (US 6,289,251, hereinafter "Huepenbecker").

4. In regards to claims 29, 34, 35, 41, and 43, Osypka discloses the essential features of the claimed invention including an electrical lead (312) with a lumen extending therethrough (Fig. 7) and a distal exit port distal of the one or more distal electrodes (322a and 322b); and an anchoring device (Fig. 11) including a self-expanding anchor (60) and an elongate tether comprising a polymeric cord (14)

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extending proximally from the anchor, extending through the proximal entry port of the lead (Fig. 7), and wherein the tether is longitudinally movable in the lumen of the lead such that the lead may be advanced over the tether (Fig. 9). Osypka does not disclose that the tether is tied by knot or swaged to the anchor. Huepenbecker teaches attaching anchors to tethers by tying by knot or swaging (col. 4, lines 19-26) to provide the predictable result of securely fixing an anchor with conventional means. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Osypka's invention by attaching the anchor to the tether by tying by knot or swaging to provide the predictable result of securely fixing an anchor with conventional means.

5. In regards to claims 30, 36, and 42, Osypka discloses a connector for limiting longitudinal movement between the lead and anchoring device (col. 7, lines 2-6; by limiting movement between the tether and anchor, movement is limited between the lead and anchor), and is insertable into the lead before the tether is deployed.

6. In regards to claims 40 and 46, the tether is detachable from the lead using, e.g., scissors or wire cutters.

7. In regards to claims 47-49, the lead is an implantable pacing lead (col. 1, line 15). In regards to claims 32, 38, and 44, Osypka's modified invention discloses the essential features of the claimed invention except for a tether that comprises a braid. It is well known in the pacing arts to provide tethers, such as Osypka's, with braids, such as braided conductors, to provide the predictable results of strong and flexible lead elements that resist breaking. Therefore, it would have been obvious to one having

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ordinary skill in the art at the time the invention was made to further modify Osypka's invention by providing a tether comprising a braid to provide the predictable results of strong and flexible lead elements that resist breaking.

Response to Arguments

8. Applicant's arguments filed 1/8/2009 have been fully considered but they are not persuasive. Applicant argued that Osypka fails to disclose a polymeric cord, and provided a dictionary definition of cord ("a: a long slender flexible material usually consisting of several strands (as of thread or yarn) woven or twisted together b: the hangman's rope"). However, the Examiner respectfully disagrees that this definition controls, and even if this particular definition of "cord" did control, Osypka's invention reasonably reads on this definition. Although the supplied definition is a plain meaning of "cord," the Office is required to impart the *broadest reasonable* plain meaning to claim terms. See MPEP 2111. As such, the Examiner is also considering the plain meaning of "cord" to include electrical "cords," such as the term is used to describe e.g., household extension cords or cords that connect lamps to electrical receptacles. Osypka's element 14 falls within this definition. Further, Applicant's broad conclusory statement that "[c]learly the Osypka lead is not the same as a tether" renders it unclear as to what aspect of the supplied definition of "cord" is inconsistent Osypka's invention. The Examiner is assuming that Applicant is referring to a requirement that a "cord" consist of several strands (because Osypka's element 14 is clearly a long slender flexible material). However, even the supplied definition of "cord" indicates that this

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usage of the term refers to structures that *usually* consist of several strands, and thus contemplating some "cords" which do *not* have several strands.

9. Applicant further argued that modifying Osypka by tying the lead 14 (or outer jacket) of Osypka would result in a large knot that would render the device inoperable, and thus tying Osypka's lead into a knot is contrary to the teachings of the reference. However, the claim language does not require that the tether itself be tied into a knot, but merely that the tether is *tied by a knot* to the anchor. For instance, a boat can be *tied by knot* to a dock without the boat itself being tied into a knot. Similarly, the teaching of Huepenbecker (Fig. 4) contemplates an anchor *tied by knot* (via element 50; col. 4, lines 19-25) to a tether/lead that does not require any sort of tying of the lead/tether itself. The examiner maintains that providing a similar sort of anchor attachment means to Osypka's invention would have been *prima facie* obvious at the time of invention, as detailed above.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

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/Angela D Sykes/

Supervisory Patent Examiner, Art Unit 3762